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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,367	03/10/2004	Janel E. Young	ETH5095CIP	4470

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1613	

NOTIFICATION DATE	DELIVERY MODE
12/22/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/797,367	YOUNG ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1613	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28,30-32,34,39 and 41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28,30-32,34,39 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. In view of the Appeal Brief filed on 08/09/2010, PROSECUTION IS HEREBY REOPENED. New grounds of rejection set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Brian-Yong S Kwon/

Supervisory Patent Examiner, Art Unit 1613.

Upon further consideration, the prior art US 6,239,177 to Mori et al. is used in the rejection below because the composition of claim 28 contains optional therapeutic agent that reads on the penetration enhancers of Mori.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 39 recited PLURONIC. PLURONIC is a trade name.

5. Claim 39 contains the trademark/trade name PLURONIC. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe nonionic triblock copolymers of (polyoxyethylene)(polyoxypropylene)(polyoxyethylene) and, accordingly, the identification/description is indefinite.

6. Trademark designates source not content. A product could change formula, and still maintain the mark, hence rendering the claimed invention indefinite.

7. Applicant may overcome the rejection by removing the trademark form the claims.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 28, 30, 31, 32 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Mori et al. (US 6,239,177 B1).

10. Mori discloses composition in the form of patch or film (column 5, lines 13 and 58-65), the composition comprises tranilast (see the whole document with emphasis on the abstract; column 2, line 40; column 3, lines 39-51), solubilizer, absorption aid and dispersant for enhancing the absorption of tranilast into the skin (abstract; column 3, lines 55 to column 5, line 19), and water soluble polymers for adhesives, the polymers are selected from polyacrylic acid and acrylate copolymer, cellulose, gelatin, casein, polyvinyl alcohol, polyvinylpyrrolidone, polyethylene glycol, naturally occurring polysaccharide and can be used alone or in combination of two or more; fat soluble polymers can also be used as the adhesive (abstract; column 5, lines 20-47).

11. The tranilast meets the tranilast of claims 28, 31 and 32. Claims 31 and 32 are directed to the properties/characteristics of the composition.

12. The adhesive material such as the polyvinyl alcohol meets the requirements for biodegradable polymer of claim 28 and the polyvinyl alcohol of claim 30. When the adhesive material is a gum arabic or polysaccharide or gelatin, the biodegradable polymer of claim 39 is met.

13. The solubilizer, absorption aid and dispersant for enhancing the absorption of tranilast into the skin meet the limitation of the optional therapeutic agent of claim 28.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al. (US 6,239,177 B1).

17. Mori is described above as anticipating claim 28. Mori discloses that it is has been known the effective concentration of tranilast on the skin tissue for treating keloid is about 8-10 μm/g. The %amount of tranilast in the composition of Mori is anticipated at 0.05 to 5 wt% of the composition.

18. Mori does not disclose the amount of tranilast in the composition in terms of mg/kg bodyweight recited in claim 34. However, taken the general teaching of Mori regarding use of tranilast to treat keloid or allergic dermatitis, one having ordinary skill in the art at the time the invention was made would be motivated to optimize the composition of Mori by using amounts of tranilast that would be effective in the treatment. In the absence of factual showing, amount of tranilast in the broad range of 0.01 mg/kg body weight to 3000 mg/kg bodyweight recited in claim 34 is not inventive over the teaching of Mori.

19. Claims 28 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al. (US 6,239,177 B1) as evidenced by Isaji et al. ("Tranilast: A New Application in the Cardiovascular Field as An Antiproliferative Drug," in Cardiovascular Drug Reviews, Vol. 16, No. 3, pp. 288-299, provided by applicant on an IDS) in view of Pope et al. (US 5,948,822).

20. Mori has been described above to anticipate claim 28. Mori's composition contains tranilast which an antiproliferative agent according to Isaji. Mori contemplates treating keloid, hypertrophic scar and allergic dermatitis by topically applying the composition containing tranilast (column 2, lines 61-67).

21. Mori does not have a second agent that is also an antiproliferative agent as required by claim 41. However, Pope discloses antiproliferative agent that reduces hyperproliferative keloid formation (column 3, lines 12-34; column 5, lines 1, 2, 6 and 7).

22. Therefore, given the general teachings of Mori and Pope, one having ordinary skill in the art at the time the invention was made would be motivated to add a second antiproliferative agent to the tranilast containing composition of Mori with a reasonable

expectation that the antiproliferative agent and tranilast would act in synergy for effectively treating hyperproliferative keloid formation.

Response to Arguments of 9/22/09

23. Applicant's arguments filed 9/22/09 have been fully considered but they are not persuasive.

24. Applicant's argument against Mori at pages 6 and 7 of the remarks is that Mori's composition contains other than tranilast and biodegradable polymer while the instant composition does not contain solubilizer, dispersant, an absorption aid and an adhesive and water.

25. The examiner disagrees with the applicant that Mori does not teach instant composition. The examiner agrees that the composition of Mori contains adhesive. But the adhesive of Mori is the biodegradable polymer of the instant claims. The examiner agrees that the composition of Mori contains contain solubilizer, dispersant, an absorption aid, but these agent meet the limitation of the optional therapeutic agent of claim 28 that enhances absorption of the tranilast into the skin for the therapeutic effect. With regards to the water, the examiner notes that the patch or film of Mori does not contain water.

Double Patenting

26. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not

identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

27. Claims 28, 30-32 and 39-41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14, 19, 21-23, 27, 28, 31, 34, 37, 39-41 of copending Application No. 10/780,452 (US 20050181023) in view of Chandrasekar et al. ("Platelets and Restenosis," in Journal of the American College of Cardiology, Vo. 35, No. 2, 2000, pp 555-562) or Miyazawa et al. ("Effects of pemirolast and tranilast on intimal thickening after arterial injury in the rat," in Journal of Cardiovascular Pharmacology, Vol. 30, no. 2, Aug. 1997).

28. The compositions of copending claims 14, 19, 21-23, 27, 28, 31, 34, 37, 39-41 of application number 10/780,452 contain Pemirolast instead of Tranilast. Both the Pemirolast and the tranilast have the functionality of inhibiting post-operative adhesion. It is however known in the art that both tranilast and pemirolast are antiallergic agents known to reduce intimal thickening as disclosed by Chandrasekar (first full paragraph, left column of page 559) and Miyazawa (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use pemirolast in place of tranilast with the expectation that the composition would reduce intimal thickening. One having ordinary skill in the art would have been motivated to use tranilast or pemirolast to reduce intimal thickening with the expectation to either would reduce intimal thickening.

29. This is a provisional obviousness-type double patenting rejection.

30. Claims 28, 30-32 and 39-41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 11, 14-16, 19, 21-25, 27-34, 37, 40 and 41 of copending Application No. 12/021,546 (US 20080119494) in view of Chandrasekar et al. ("Platelets and Restenosis," in Journal of the American College of Cardiology, Vo. 35, No. 2, 2000, pp 555-562) or Miyazawa et al. ("Effects of pemirolast and tranilast on intimal thickening after arterial injury in the rat," in Journal of Cardiovascular Pharmacology, Vol. 30, no. 2, Aug. 1997).

31. The method of copending claims 1-6, 11, 14-16, 19, 21-25, 27-34, 37, 40 and 41 of 10/780,452 uses compositions that contain Pemirolast instead of Tranilast. Both the Pemirolast and the tranilast have the functionality of inhibiting post-operative adhesion. It

is however known in the art that both tranilast and pemirolast are antiallergic agents known to reduce intimal thickening as disclosed by Chandrasekar (first full paragraph, left column of page 559) and Miyazawa (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use pemirolast in place of tranilast with the expectation that the composition would reduce intimal thickening. One having ordinary skill in the art would have been motivated to use tranilast or pemirolast to reduce intimal thickening with the expectation to either would reduce intimal thickening or post operative adhesions.

32. This is a provisional obviousness-type double patenting rejection.

33. No claim is allowed.

34. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

35. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Y. Kwon can be reached on (571) 272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

36. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Primary Examiner, Art Unit 1613